

CLAIM AMENDMENTS

IN THE CLAIMS

This listing of the claims will replace all prior versions, and listing, of claims in the application or previous response to office action:

1-63. (Cancelled)

64. **(Currently Amended)** A method of suppressing the interference of a masking agent selected from the group consisting of a leukocyte esterase, a heme protein, a myoglobin analogue, a hemoglobin analogue, a myoglobin derivative, a hemoglobin derivative, a myoglobin oxidation product, a hemoglobin oxidation product, a myoglobin breakdown product, a hemoglobin breakdown product, a ferritin, methemoglobin, sulfhemoglobin, and bilirubin, on a molecular assay of a nucleic acid-containing test sample, the method comprising:

contacting the test sample with a reagent consisting of from about 0.01 M to about 0.1 M of a divalent metal chelator and from about 0.1 M to 1.0 M of a chelator enhancing component selected from the group consisting of lithium chloride, sodium salicylate, and combinations thereof; and

~~wherein the interference of the masking agent on the molecular assay of the nucleic acid-containing test sample is suppressed.~~

~~storing the sample at a temperature of from about 4°C to about 37°C for a time of up to about 7 days.~~

65. (Previously Presented) A method according to claim 64, wherein the divalent metal chelator is selected from the group consisting of ethylenediaminetetraacetic acid, imidazole, ethylenebis(oxyethylenenitriol)tetraacetic acid; iminodiacetate; and 1,2-bis(2 aminophenoxy)ethane-N,N,N',N' -tetraacetic acid; *bis*(5-amidino-2-benzimidazolyl)methane and salts thereof.

66. (Previously Presented) A method according to claim 64 further comprising contacting the test sample with a buffer.

67. (Currently Amended) A method of suppressing the interference of a masking agent selected from the group consisting of a leukocyte esterase, a heme protein, a myoglobin analogue, a hemoglobin analogue, a myoglobin derivative, a hemoglobin derivative, a myoglobin oxidation product, a hemoglobin oxidation product, a myoglobin breakdown product, a hemoglobin breakdown product, a ferritin, methemoglobin, sulfhemoglobin, and bilirubin, on a molecular assay of a nucleic acid-containing test sample, the method comprising:

contacting the test sample with a reagent having from about 0.01 M to about 0.1 M of a divalent metal chelator and from about 0.1 M to 1.0 M of a chelator enhancing component selected from the group consisting of lithium chloride, sodium salicylate, sodium perchlorate, sodium thiocyanate, and combinations thereof; and

~~wherein the interference of the masking agent on the molecular assay of the nucleic acid-containing test sample is suppressed.~~

storing the sample at a temperature of from about 4°C to about 37°C for a time of up to about 7 days.

68. (Previously Presented) A method according to claim 67, wherein the divalent metal chelator is selected from the group consisting of ethylenediaminetetraacetic acid, imidazole, ethylenebis(oxyethylenenitriol)tetraacetic acid; iminodiacetate; and 1,2-bis(2 aminophenoxy)ethane-N,N,N',N' -tetraacetic acid; *bis*(5-amidino-2-benzimidazolyl)methane and salts thereof.

69. (Previously Presented) A method according to claim 67, wherein the divalent metal chelator is selected from the group consisting of ethylenediaminetetraacetic acid and 1,2-bis(2-aminophenoxy)ethane-N,N,N',N'-tetraacetic acid, and salts thereof.

70. (Previously Presented) A method according to claim 67, wherein the masking agent is selected from the group consisting of a leukocyte esterase and a heme protein.

71. (Withdrawn) A method according to claim 67, wherein the heme protein is selected from the group consisting of a myoglobin analogue, a hemoglobin analogue, a myoglobin oxidation product, a hemoglobin oxidation product, a myoglobin breakdown product, and a hemoglobin breakdown product.

72. (Withdrawn) A method according to claim 67, wherein the masking agent is selected from the group consisting of a ferritin, methemoglobin, sulfhemoglobin and bilirubin.

73. (Withdrawn) A method according to claim 67, wherein the masking agent is selected from the group consisting of methemoglobin and bilirubin.

74. (Previously Presented) A method according to claim 67 further comprising contacting the nucleic acid-containing test sample with an amount of at least one enzyme inactivating component selected from the group consisting of manganese chloride, sarkosyl, and sodium dodecyl sulfate in the range of up to about 5% molar concentration.

75. (Previously Presented) A method according to claim 67, wherein the nucleic acid is selected from the group consisting of DNA, RNA, mRNA, and cDNA.

76. (Previously Presented) A method according to claim 67, wherein the nucleic acid is eukaryotic DNA.

77. (Previously Presented) A method according to claim 67, wherein the molecular assay is selected from the group consisting of a polymerase chain reaction, a ligase chain reaction, nucleic acid sequence-based amplification, strand displacement amplification, and a genetic transformation test.

78. (Previously Presented) A method according to claim 67, wherein the molecular assay comprises a polymerase chain reaction.

79. (Currently Amended) A method of improving the signal response of a molecular assay of a nucleic acid-containing test sample, the method comprising:

contacting the nucleic acid-containing test sample with a reagent consisting of from about 0.01 M to about 0.1 M of a divalent metal chelator and from about 0.1 M to 1.0 M of a chelator enhancing component selected from the group consisting of lithium chloride, sodium salicylate, and combinations thereof to form a preserved test sample, wherein the interference of a masking agent selected from the group consisting of a leukocyte esterase, a heme protein, a myoglobin analogue, a hemoglobin analogue, a myoglobin derivative, a hemoglobin derivative, a myoglobin oxidation product, a hemoglobin oxidation product, a myoglobin breakdown product, a hemoglobin breakdown product, a ferritin, methemoglobin, sulfhemoglobin, and bilirubin on the molecular assay is suppressed;

storing the preserved test sample at a temperature of from about 4°C to about 37°C for a time of up to about 7 days;

extracting molecular analytes of interest from the preserved test sample; and

conducting a molecular assay on the extracted molecular analytes of interest, wherein the signal response of the molecular assay is improved relative to a molecular assay performed without the reagent.

80. (Previously Presented) A method according to claim 79, wherein the divalent metal chelator is selected from the group consisting of ethylenediaminetetraacetic acid, imidazole, ethylenebis(oxyethylenenitriol)tetraacetic acid; iminodiacetate; and 1,2-bis(2-aminophenoxy)ethane-N,N,N',N'-tetraacetic acid; *bis*(5-amidino-2-benzimidazolyl)methane and salts thereof.

81. (Previously Presented) A method according to claim 79 further comprising contacting the test sample with a buffer.

82. (Currently Amended) A method of improving the signal response of a molecular assay of a nucleic acid-containing test sample, the method comprising:

contacting the nucleic acid-containing test sample with a reagent having from about 0.01 M to about 0.1 M of a divalent metal chelator and from about 0.1 M to 1.0 M of a chelator enhancing component selected from the group consisting of lithium chloride, sodium salicylate, sodium perchlorate, sodium thiocyanate, and combinations thereof to form a preserved test sample, wherein the interference of a masking agent selected from the group consisting of a leukocyte esterase, a heme protein, a myoglobin analogue, a hemoglobin analogue, a myoglobin derivative, a hemoglobin derivative, a myoglobin oxidation product, a hemoglobin oxidation product, a myoglobin breakdown product, a hemoglobin breakdown product, a ferritin, methemoglobin, sulfhemoglobin, and bilirubin on the molecular assay is suppressed;

storing the preserved test sample at a temperature of from about 4°C to about 37°C for a time of up to about 7 days;

extracting molecular analytes of interest from the preserved test sample; and

conducting a molecular assay on the extracted molecular analytes of interest, wherein the signal response of the molecular assay is improved relative to a molecular assay performed without the reagent.

83. (Previously Presented) A method according to claim 82, wherein the divalent metal chelator is selected from the group consisting of ethylenediaminetetraacetic acid, imidazole, ethylenebis(oxyethylenenitriol)tetraacetic acid; iminodiacetate; and 1,2-bis(2-aminophenoxy)ethane-N,N,N',N'-tetraacetic acid; *bis*(5-amidino-2-benzimidazolyl)methane and salts thereof.

84. (Previously Presented) A method according to claim 82, wherein the divalent metal chelator is selected from the group consisting of ethylenediaminetetraacetic acid and 1,2-bis(2-aminophenoxy)ethane-N,N,N',N'-tetraacetic acid, and salts thereof.

85. (Previously Presented) A method according to claim 82, wherein the masking agent is selected from the group consisting of a leukocyte esterase and a heme protein.

86. (Withdrawn) A method according to claim 85, wherein the heme protein is selected from the group consisting of a myoglobin analogue, a hemoglobin analogue, a myoglobin oxidation product, a hemoglobin oxidation product, a myoglobin breakdown product, and a hemoglobin breakdown product.

87. (Withdrawn) A method according to claim 82, wherein the masking agent is selected from the group consisting of a ferritin, methemoglobin, sulfhemoglobin and bilirubin.

88. (Withdrawn) A method according to claim 82, wherein the masking agent is selected from the group consisting of methemoglobin and bilirubin.

89. (Previously Presented) A method according to claim 82 wherein the nucleic acid-containing test sample is further contacted with an amount of at least one enzyme inactivating component selected from the group consisting of manganese chloride, sarkosyl, and sodium dodecyl sulfate in the range of up to about 5% molar concentration.

90. (Previously Presented) A method according to claim 82 wherein the nucleic acid-containing test sample is a bodily fluid.

91. (Previously Presented) A method according to claim 90, wherein the bodily fluid is selected from the group consisting of urine, blood, blood serum, amniotic fluid; cerebrospinal and spinal fluid; synovial fluid; conjunctival fluid; salivary fluid; vaginal fluid; stool; seminal fluid; lymph; bile; tears, and sweat.

92. (Previously Presented) A method according to claim 91, wherein the bodily fluid is urine.

93. (Previously Presented) A method according to claim 82, wherein the nucleic acid is selected from the group consisting of DNA, RNA, mRNA, and cDNA.

94. (Previously Presented) A method according to claim 82, wherein the nucleic acid is eukaryotic DNA.

95. (Previously Presented) A method according to claim 82, wherein the molecular assay is selected from the group consisting of a polymerase chain reaction, a ligase chain reaction, nucleic acid sequence-based amplification, strand displacement amplification, and a genetic transformation test.

96. (Previously Presented) A method according to claim 82, wherein the molecular assay comprises a polymerase chain reaction.

97. (New) A method of suppressing the interference of a masking agent selected from the group consisting of a leukocyte esterase, a heme protein, a myoglobin analogue, a hemoglobin analogue, a myoglobin derivative, a hemoglobin derivative, a myoglobin oxidation product, a hemoglobin oxidation product, a myoglobin breakdown product, a hemoglobin breakdown product, a ferritin, methemoglobin, sulfhemoglobin, and bilirubin, on a molecular assay of a nucleic acid-containing test sample, the method comprising:

contacting the test sample with a reagent consisting of from about 0.01 M to about 0.1 M of a chelator selected from the group consisting of ethylenediaminetetraacetic acid, imidazole, ethylenebis(oxyethylenenitriol)tetraacetic acid; iminodiacetate; and 1,2-bis(2 aminophenoxy)ethane-N,N,N',N' -tetraacetic acid; *bis*(5-amidino-2-benzimidazolyl)methane and salts or combinations thereof, and from about 0.1 M to 1.0 M of a chelator enhancing component selected from the group consisting of lithium chloride, sodium salicylate, and combinations thereof;

storing the sample at a temperature of from about 4°C to about 37°C for a time of up to about 7 days;

thereby suppressing the interference of the masking agent on the molecular assay of the nucleic acid-containing test sample.

98. (New) A method of performing a molecular assay on a nucleic acid-containing test sample, the method comprising:

suppressing the interference of a masking agent in the sample wherein the masking agent is selected from the group consisting of a leukocyte esterase, a heme protein, a myoglobin analogue, a hemoglobin analogue, a myoglobin derivative, a hemoglobin derivative, a myoglobin oxidation product, a hemoglobin oxidation product, a myoglobin

breakdown product, a hemoglobin breakdown product, a ferritin, methemoglobin, sulfhemoglobin, and bilirubin, the suppressing comprising:

contacting the test sample with a reagent consisting of from about 0.01 M to about 0.1 M of a chelator selected from the group consisting of ethylenediaminetetraacetic acid, imidazole, ethylenebis(oxyethylenenitriol)tetraacetic acid; iminodiacetate; and 1,2-*bis*(2-aminophenoxy)ethane-N,N,N',N'-tetraacetic acid; *bis*(5-amidino-2-benzimidazolyl)methane and salts or combinations thereof, and from about 0.1 M to 1.0 M of a chelator enhancing component selected from the group consisting of lithium chloride, sodium salicylate, and combinations thereof;

storing the sample at a temperature of from about 4°C to about 37°C for a time of up to about 7 days; and

performing the molecular assay on the test sample wherein the masking agent is suppressed.